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# REPOSITIONING WIRES AND METHODS FOR REPOSITIONING PROSTHETIC HEART VALVE DEVICES WITHIN A HEART CHAMBER AND RELATED SYSTEMS, DEVICES AND METHODS

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application Ser. No. 62/731,230, filed Sep. 14, 2018 and entitled REPOSITIONING WIRES AND METHODS FOR REPOSITIONING PROSTHETIC HEART VALVE DEVICES WITHIN A HEART CHAMBER, the entire contents of which are incorporated herein by reference.

## STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable

## INCORPORATION BY REFERENCE

All references, including but not limited to publications, patent applications and patents mentioned in this specification are hereby incorporated by reference to the same extent and with the same effect as if each reference was specifically and individually indicated to be incorporated by reference.

## FIELD OF THE INVENTION

The inventions described herein relate to delivery systems, devices and methods for delivering and/or positioning a cardiac valve.

## BACKGROUND OF THE INVENTION

The human heart comprises four chambers and four heart valves that assist in the forward (antegrade) flow of blood through the heart. The chambers include the left atrium, left ventricle, right atrium and right ventricle. The four heart valves include the mitral valve, the tricuspid valve, the aortic valve and the pulmonary valve.

The mitral valve is located between the left atrium and left ventricle and helps control the flow of blood from the left atrium to the left ventricle by acting as a one-way valve to prevent backflow into the left atrium. Similarly, the tricuspid valve is located between the right atrium and the right ventricle, while the aortic valve and the pulmonary valve are semilunar valves located in arteries flowing blood away from the heart. The valves are all one-way valves, with leaflets that open to allow forward (antegrade) blood flow. The normally functioning valve leaflets close under the pressure exerted by reverse blood to prevent backflow (retrograde) of the blood into the chamber it just flowed out of.

Native heart valves may be, or become, dysfunctional for a variety of reasons and/or conditions including but not limited to disease, trauma, congenital malformations, and aging. These types of conditions may cause the valve structure to either fail to properly open (stenotic failure) and/or fail to close properly (regurgitant).

Mitral valve regurgitation is a specific problem resulting from a dysfunctional mitral valve. Mitral regurgitation results from the mitral valve allowing at least some retrograde blood flow back into the left atrium from the right atrium. This backflow of blood places a burden on the left

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ventricle with a volume load that may lead to a series of left ventricular compensatory adaptations and adjustments, including remodeling of the ventricular chamber size and shape, that vary considerably during the prolonged clinical course of mitral regurgitation.

Native heart valves generally, e.g., mitral valves, therefore, may require functional repair and/or assistance, including a partial or complete replacement. Such intervention may take several forms including open heart surgery and open heart implantation of a replacement heart valve. See e.g., U.S. Pat. No. 4,106,129 (Carpentier), for a procedure that is highly invasive, fraught with patient risks, and requiring not only an extended hospitalization but also a highly painful recovery period.

Less invasive methods and devices for replacing a dysfunctional heart valve are also known and involve percutaneous access and catheter-facilitated delivery of the replacement valve. Most of these solutions involve a replacement heart valve attached to a structural support such as a stent, commonly known in the art, or other form of wire network designed to expand upon release from a delivery catheter. See, e.g., U.S. Pat. No. 3,657,744 (Ersek); U.S. Pat. No. 5,411,552 (Andersen). The self-expansion variants of the supporting stent assist in positioning the valve, and holding the expanded device in position, within the subject heart chamber or vessel. This self-expanded form also presents problems when, as is often the case, the device is not properly positioned in the first positioning attempt and, therefore, must be recaptured and positionally adjusted. This recapturing process in the case of a fully, or even partially, expanded device requires re-collapsing the device to a point that allows the operator to retract the collapsed device back into a delivery sheath or catheter, adjust the inbound position for the device and then re-expand to the proper position by redeploying the positionally adjusted device distally out of the delivery sheath or catheter. Collapsing the already expanded device is difficult because the expanded stent or wire network is generally designed to achieve the expanded state which also resists contractive or collapsing forces.

Besides the open heart surgical approach discussed above, gaining access to the valve of interest is achieved percutaneously via one of at least the following known access routes: transapical; transfemoral; transatrial; and transseptal delivery techniques.

Generally, the art is focused on systems and methods that, using one of the above-described known access routes, allow a partial delivery of the collapsed valve device, wherein one end of the device is released from a delivery sheath or catheter and expanded for an initial positioning followed by full release and expansion when proper positioning is achieved. See, e.g., U.S. Pat. No. 8,852,271 (Murray, III); U.S. Pat. No. 8,747,459 (Nguyen); U.S. Pat. No. 8,814,931 (Wang); U.S. Pat. No. 9,402,720 (Richter); U.S. Pat. No. 8,986,372 (Murray, III); and U.S. Pat. No. 9,277,991 (Salahieh); and U.S. Pat. Pub. Nos. 2015/0272731 (Racchini); and 2016/0235531 (Ciobanu).

However, known delivery systems, devices and methods still suffer from significant flaws in delivery methodology including, inter alia, positioning, repositioning and/or recapture capability and efficiency.

Various embodiments of the several inventions disclosed herein address these, inter alia, issues.

## BRIEF SUMMARY OF THE INVENTION

The invention provides methods, devices and systems for delivering, positioning and/or repositioning an expandable